

**Remarks**

**I. Objection to the specification and claims**

Claims 1-15 are pending in this application. The Examiner objected to the specification and objected to all claims. In the objection, the Examiner requested that applicants amend the specification to explicitly state, with reference to the terms and phrases of claim elements reciting "means," what structure, materials and acts perform the function recited.

The Examiner's comments express concern about what structures correspond to certain "means" recited in the claims. Applicants do not agree that the specification needs to be amended to make those structures clear. Instead, the structures are clear from the original disclosure. The claims include reference to an actuating means, a first sealing means, a second sealing means and a means for pressing. See, e.g., claims 1, 3, 7 and 12. The description at page 3, lines 23-26 identifies structure for the actuating means. The application at page 5, lines 25-28 describes structure for the first sealing means. Structure for the second sealing means is disclosed at page 6, lines 11-13. Moreover, with reference to the Figures, the application at page 7, lines 8-9 discloses an actuating means (7), at page 7, lines 21-23 discloses a first sealing means (18) and at page 7, lines 25-27 discloses a second sealing means (19). Lastly, the application at page 8, lines 22-23 and Figures 7-9 discloses structure acceptable as means for pressing.

In view of this explanation, applicants respectfully request that the Examiner withdraw the objections.

**II. Rejections under 35 U.S.C. § 102**

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,201,308 to Newhouse, U.S. Patent No. 5,447,151 to Bruna et al., or WO 92/18188. The Examiner stated that the documents disclose powder inhalers comprising each element of the claimed invention. Applicants respectfully traverse these rejections.

With respect to WO 92/18188, the Examiner particularly cited the bottom of page 8 of the publication as a disclosure of a closure member in the form of the walls of the

apertures (8), which seal against the shaft (3) to seal the air channel (10) around the metering member in a substantially waterproof manner. Applicants do not agree that the document teaches a closure element adapted to plug the air channel around the metering member in a substantially water-proof manner as recited in claim 1. Instead, and as can be seen in Figure 4 of the publication, for example, the walls around apertures (8) are adapted to plug only the medicament container from moisture. The air channel (10) is not plugged and moisture appears free to enter the air channel (10) and the metering member (3).

Absent a disclosure of at least the closure element adapted to plug the air channel around the metering member, WO 92/18188 should not anticipate claim 1. Rejected claims 2, 9 and 10, which depend from claim 1, incorporate the same closure element limitation and are patentable over the document for the same reasons discussed above. In the rejection of those dependent claims, the Examiner referred to Figures 1 and 14 of WO 92/18188. Applicants note that the document does not contain a Figure 14.

With respect to the Bruna and Newhouse patents, the Examiner stated that the documents disclose a closure member that takes the form of a one-way valve that closes off the air passage through which air is drawn until such time as inhalation begins. The Examiner particularly cited valve (85) of Bruna and valve (44) of Newhouse. The one-way flap valves of Bruna and Newhouse are not disclosed as effectively protecting the air channel around the metering member from moisture. Furthermore, claim 1 of the present invention recites that the closure element is adapted to plug the air channel when the metering member is in the filling position and to open the air channel when the metering member is in the inhalation position. This requirement does not appear to be necessarily met using the one-way flap valves of Bruna and Newhouse, where the air channel is opened only in response to the inhalation effort of the patient. For at least these reasons, the documents should not anticipate claim 1. Rejected claims 3 and 9-11, which depend from claim 1, incorporate the limitations of claim 1 and are patentable over the cited documents for the same reasons discussed above.

In view of these comments, applicants respectfully request that the Examiner withdraw the novelty rejections of claims 1-3 and 9-11.

### **III. Rejections under 35 U.S.C. § 103(a)**

Claims 12 and 13 were rejected under 35 U.S.C. § 103(a) over the disclosure of Bruna in view of WO 90/02576. The Examiner stated that Bruna discloses powder inhalers having all features recited in claim 12 except the recited second sealing means. The Examiner concluded that it would have been obvious to include a certain sealing means from the inhalers disclosed in WO 90/02576 into the inhalers of Bruna to make the claimed inventions.

As explained in response to the novelty rejections, Bruna does not teach the features of claim 1, and as a result does not teach the features of claim 12. The combination of the additional cited sealing means of WO 90/02576 with the disclosure of Bruna therefore would not suggest the inventions of claims 12 or 13. Moreover, the one-way valves of Bruna positions into the inhalation channel are generally undesirable as they can be susceptible to jamming or capturing of drug particles and may even hamper the inhalation process in asthmatic patients having reduced lung capacity. In particular, the one-way valve (85) of Fig. 3 in Bruna can be sealed against the shoulder shown in Fig. 3 only by applying pressure on the valve member, e.g., by means of a spring, such that the surfaces are pressed tightly against each other. That structure can seriously hamper the efforts of an asthmatic patient having reduced lung capacity to produce an air stream sufficient to aerosolize the powdered medicament. In contrast, in the device of the present invention, an effective seal can be achieved without compromising the free flow of an air stream in the air channel.


Lastly, claim 14 was rejected as being unpatentable over WO 92/18188. The Examiner stated that it would have been obvious to modify the device of the publication to include additional sealing means in order to better ensure a substantially waterproof seal around the metering member. This rejection assumes that WO 92/18188 teaches the invention of claim 1. As explained above, however, the document does not disclose a closure element adapted to plug the air channel around the metering member in a substantially water-proof manner. Instead, and as can be seen in Figure 4 of the

publication, for example, the walls around apertures (8) are adapted to plug only the medicament container from moisture. The air channel (10) is not plugged and moisture appears free to enter the air channel (10) and the metering member (3). This disclosure does not teach or suggest the invention of claim 1, and therefore does not teach or suggest the invention of claim 14.

Applicants acknowledge the Examiner's finding of allowability for claims 4-8 and 15 if re-written in independent form. In view of the comments above, the remaining claims should also be allowable over the disclosures of the cited documents. If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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